## REMARKS

Claims 1-20 are now pending in the application. Claims 1, 13, and 17 have been amended to recite that the arterial graft lead end is configured for connection to the artery by anastomosis and the venous outflow catheter depositing end is configured for insertion through a vein and into the right atrium. Claims 1, 13, and 17 have also been amended to recite that the cuff inlet is in fluid communication with the cuff outlet and that the cuff directs passage of blood from the arterial graft to the venous outflow catheter. Support for the amendments is found throughout the Specification and Figures, and at least at Paragraphs [0025], [0026], [0030], and [0034]. Claim 17 has been amended to recite a surgical insertion of the arteriovenous shunt. Support for the amendment is found throughout the Specification and at least at Paragraphs [0029] and [0030]. Minor amendments have been made to claim 7 to overcome the §112 rejection and to claims 2, 12, 14, and 18 to provide proper antecedent basis. The amendments to the claims contained herein are of equivalent scope as originally filed and, thus, are not narrowing amendments. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### REJECTION UNDER 35 U.S.C. § 112

Claim 7 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended the claim to replace the Teflon and Dacron trade names with the respective chemical names of polytetrafluoroethylene and polyethylene terephthalate. Accordingly, reconsideration and removal of the rejection are respectfully requested.

**REJECTIONS UNDER 35 U.S.C. § 102**

Claims 1-4, 6, 8, 10-11, 13, 15-17, and 19-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cohn et al. (U.S. Pat. No. 6,099,542). This rejection is respectfully traversed.

At the outset, Applicants note that claims 1, 13, and 17 have been amended to recite that the arterial graft lead end is configured for connection to the artery by anastomosis and the venous outflow catheter depositing end is configured for insertion through a vein and into the right atrium. Claims 1, 13, and 17 have also been amended to recite that the cuff inlet is in fluid communication with the cuff outlet and that the cuff directs passage of blood from the arterial graft to the venous outflow catheter.

Cohn discloses a percutaneous arteriovenous fistula catheter (PAFC) and a non-surgical radiological method for on-demand generation of fistulas between "closely associated" or "immediately adjacent" arteries and veins (or between two veins). (Column 9, lines 3 through 23; Column 11 lines 23 through 46; and Column 22, line 2). The Cohn methodology joins the artery and vein without synthetic or artificially introduced means. (Column 11, lines 34 through 47). The fistula is formed by aligning a venous catheter and an arterial catheter in a vein and an immediately adjacent artery. Aligned openings are formed in the vein and the immediately adjacent artery by concurrent electrical vaporization of the vascular tissues or by using a microscalpel. (Column 20, lines 43 through Column 21, line 41). Vascular engorgement at the opening sites forms a fistula between the immediately adjacent venous and arterial openings and blood flows from the arterial opening to the venous opening. (Column 25, lines 8 through 12; and Column 11, line 48 through Column 12, line 10).

With respect to claims 1 and 13 and the respective dependents thereon, there are at least three distinct differences between the Cohn percutaneous arteriovenous fistula catheter and related methodologies and Applicants' claimed invention.

First, the Cohn vascular connection device is a fistula; it is not a shunt. The Cohn fistula is not a "synthetic or artificially introduced means for joining or attaching the perforated vein to the perforated artery..." (Column 11, lines 37 through 42). The fistula is instead formed by engorgement of the immediately adjacent veins or immediately adjacent artery and vein. (Column 11, line 48 through Column 12, line 10). In further support of the differences between fistula connections and shunt connections, Cohn provides great detail distinguishing a shunt from a fistula and touting the benefits of the Cohn non-artificial vascular connections and methodology over the use of shunts. (Column 5, lines 8 through 38; and Column 30, lines 18 through 20).

Second, Cohn does not disclose a cuff in fluid communication with an arterial graft and a venous catheter to direct blood flow from the arterial graft to the venous catheter. With respect to the embodiments and teachings to which the Examiner equates to Applicants' cuff, Applicants respectfully point out that the temporary connection of electrical leads to pass an electrical current is neither a fluid communication, nor is it a means by which to facilitate blood flow from an arterial graft to a venous catheter. The Cohn connection of electrical leads to pass an electrical current does not function to provide fluid communication between the venous catheter and the arterial graft. Additionally, the electrical leads are small subcomponents housed within and deployed from the Cohn arterial catheter and the venous catheter. To the contrary, Applicants' cuff is sized to house both the arterial graft and the venous outflow catheter. Further with respect to the placement of the venous catheter and the arterial graft, Applicants' device is configured to

connect the arterial graft to the artery by anastomosis and the venous outflow catheter is configured for insertion through a vein and into the right atrium of the heart. Applicants respectfully assert that the Cohn reference is not configured to perform such functions.

Third, Applicants' vascular connection is a synthetic and implanted device to facilitate blood flow. As stated above herein, the Cohn reference specifically discloses forming the artery to vein fistula passage without a synthetic device.

With respect to the method claim 17 and dependents thereon, Cohn does not disclose Applicants' claimed methods. As stated above herein, Cohn does not disclose connecting the artery to the vein using a synthetic device or using a surgical technique. Applicants' claim recites surgically inserting an arteriovenous shunt into the patient and the shunt is a synthetic device. With respect to the location of the blood deposition, Applicants respectfully disagree with the Examiner that any desirable anatomical location can be used. To create the fistula as disclosed by Cohn would require subjecting the right atrium to an electrical current to create an intentional hole in the thick wall of the right atrium and vaporization of an artery immediately adjacent to the right atrium. The "Theoretical Support" for the Cohn disclosure and the clinical findings upon which Cohn bases all teachings indicate that the formation of fistulas from certain penetrating traumas may be insufficient to form the fistula due to the "spatial relationship existing between the injured blood vessels in-vivo." (Column 12, lines 8 through 10). Accordingly, if the perforation were too remote from the right atrium, the Cohn disclosure and teachings would fail.

Because Cohn fails to disclose each and every element of Applicants' claims as amended, the §102 rejection is improper. Reconsideration and removal of the rejection are respectfully requested.

**REJECTIONS UNDER 35 U.S.C. § 103**

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Cohn. As disclosed above, Cohn fails to disclose each and every element of Applicants' invention as claimed. Even with the knowledge of useful materials, Cohn fails to teach or suggest Applicants' arteriovenous shunt having an arterial graft configured for anastomosis to an artery, a venous outflow catheter configured for insertion through the vein and into the right atrium, and a cuff sized to fit over both an arterial graft and a venous catheter and the cuff having an inlet in fluid communication with an outlet to facilitate blood flow between the arterial graft and the venous catheter. Because Cohn fails to teach or suggest Applicants' claimed invention as amended, the §103(a) rejection is improper. Reconsideration and removal of the rejection are respectfully requested.

Claims 5 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cohn et al. in view of Squitieri (U.S. Pat. No. 6,582,409). Squitieri discloses a hemodialysis and vascular access device containing tubes of certain lengths. The combination of Squitieri and Cohn fails to teach or suggest Applicants' arteriovenous shunt having an arterial graft configured for anastomosis to an artery, a venous outflow catheter configured for insertion through the vein and into the right atrium, and a cuff sized to fit over both an arterial graft and a venous catheter and the cuff having an inlet in fluid communication with an outlet to facilitate blood flow between the arterial graft and the venous catheter. Because the combination of Cohn and Squitieri fails to teach or suggest Applicants' claimed invention as amended, the §103(a) rejection is improper.

Claims 12, 14, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cohn et al. in view of Herweck et al. (U.S. Pat. No. 5,197,976).

Applicants respectfully point out they are unsure as to which element of Herweck the Examiner is referring in the argument. Nonetheless, in light of the claims objected to, the teachings of Herweck pertaining to catheter size as combined with Cohn still fail to teach or suggest Applicants' arteriovenous shunt having an arterial graft configured for anastomosis to an artery, a venous outflow catheter configured for insertion through the vein and into the right atrium, and a cuff sized to fit over both an arterial graft and a venous catheter and the cuff having an inlet in fluid communication with an outlet to facilitate blood flow between the arterial graft and the venous catheter. Because the combination of Cohn and Herweck fails to teach or suggest Applicants' claimed invention as amended, the §103(a) rejection is improper. Reconsideration and removal of the rejection are respectfully requested.

**CONCLUSION**

Applicants submit that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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By: _____
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